Food and Drug Administration, HHS

gastroenteritis) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*; bacterial dermatitis caused by *S. aureus*, *Streptococcus* spp., and *P. mirabilis*; and soft tissues (abscesses, lacerations, and wounds) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*.

- (C) *Limitations*. Use for 5 to 7 days or 48 hours after all symptoms have subsided. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (ii) Cats—(A) Amount. 50 milligrams (5 to 10 milligrams per pound) once daily.
- (B) Indications for use. Treatment of infections caused by susceptible strains of organisms as follows: upper respiratory tract due to Staphylococcus spp., Streptococcus spp., Hemophilus spp., E. coli, Pasteurella spp., and P. mirabilis; genitourinary tract (cystitis) due to S. aureus, Streptococcus spp., E. coli, P. mirabilis, and Corynebacterium spp.; gastrointestinal tract due to E. coli, Proteus spp., Staphylococcus spp., and Streptococcus spp.; skin and soft tis-(abscesses, lacerations. and wounds) due to Staphylococcus spp., Streptococcus E. spp.. coli.and Pasteurella multocida.
- (C) *Limitations*. Use for 5 to 7 days or 48 hours after all symptoms have subsided. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
 - (2) [Reserved]
- (c) Sponsors. See Nos. 000856 and 051311 in \$510.600(c) of this chapter.
- (1) Conditions of use. Dogs—(i) Amount. 5 milligrams per pound of body weight twice daily.
- (ii) Indications for use. Treatment of bacterial dermatitis due to S. aureus, Streptococcus spp., Staphylococcus spp., and E. coli, and soft tissue infections (abscesses, wounds, lacerations) due to S. aureus, Streptococcus spp., E. coli, P. mirabilis and Staphylococcus spp.
- (iii) *Limitations*. Use for 5 to 7 days. Continue for 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[57 FR 37319, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 60 FR 55658, Nov. 2, 1995; 62 FR 13302, Mar. 20, 1997; 67 FR 67521, Nov. 6, 2002; 68 FR 54658, Sept. 18, 2003; 68 FR 55824, Sept. 29, 2003]

§ 520.88c Amoxicillin trihydrate oral suspension.

- (a) Specifications. Each 0.8-milliliter dose contains amoxicillin trihydrate equivalent to 40 milligrams of amoxicillin.
- (b) *Sponsor*. See No. 000069 in §510.600(c) of this chapter.
- (c) Related tolerances. See §556.510 of this chapter.
- (d) Conditions of use. Swine—(1) Amount. 40 milligrams orally, twice a day using a dosing pump.
- (2) Indications for use. Treatment of baby pigs under 10 pounds for porcine colibacillosis caused by Escherichia coli susceptible to amoxicillin.
- (3) Limitations. Treat animals for 48 hours after all symptoms have subsided but not beyond 5 days. Do not slaughter during treatment or for 15 days after latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37319, Aug. 18, 1992, as amended at 60 FR 55658, Nov. 2, 1995]

§ 520.88d Amoxicillin trihydrate soluble powder.

- (a) *Specifications*. Each gram contains amoxicillin trihydrate equivalent to 115.4 milligrams of amoxicillin.
- (b) Sponsor. See No. 000069 in $\S510.600$ (c) of this chapter.
- (c) Related tolerances. See §556.38 of this chapter.
- (d) Conditions of use. Preruminating calves including veal calves—(1) Amount. 400 milligrams per 100 pounds of body weight twice daily.
- (2) Indications for use. Treatment of bacterial enteritis when due to susceptible *Escherichia coli* in preruminating calves including veal calves.
- (3) Limitations. Administer by drench or by mixing in milk. Treatment should be continued for 48 hours after all symptoms have subsided but not to exceed 5 days. For use in preruminating calves including veal

§520.88e

calves only, not for use in other animals which are raised for food production. Do not slaughter animals during treatment or for 20 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37319, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 58 FR 18304, Apr. 8, 1993, as amended at 60 FR 55658, Nov. 2, 1995; 62 FR 5525, Feb. 6, 1997]

§ 520.88e Amoxicillin trihydrate

- (a) Specifications. Each bolus contains the equivalent of 400 milligrams of amoxicillin.
- (b) *Sponsor*. See No. 000069 in §510.600(c) of this chapter.
- (c) Related tolerances. See §556.38 of this chapter.
- (d) Conditions of use. Preruminating calves including veal calves—(1) Amount. 400 milligrams per 100 pounds of body weight twice daily.
- (2) Indications for use. Treatment of bacterial enteritis when due to susceptible *Escherichia coli* in preruminating calves including veal calves.
- (3) Limitations. For oral use in preruminating calves including veal calves only, not for use in other animals which are raised for food production. Treatment should be continued for 48 hours after all symptoms have subsided but not to exceed 5 days. Do not slaughter animals during treatment or for 20 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37320, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995; 62 FR 5526, Feb. 6, 1997]

§ 520.88f Amoxicillin trihydrate tablets.

- (a) *Specifications*. Each tablet contains amoxicillin trihydrate equivalent to 50, 100, 200, or 400 milligrams of amoxicillin.
- (b) Sponsors. See Nos. 000856 and 051311 in $\S510.600(c)$ of this chapter.
- (c) Conditions of use—(1) Dogs—(i) Amount. 5 milligrams per pound of body weight twice a day.
- (ii) Indications for use. Treatment of bacterial dermatitis due to Staphylococcus aureus, Streptococcus spp., Staphylococcus spp., and Escherichia

coli; and soft tissue infections (abscesses, wounds, lacerations) due to S. aureus, Streptococcus spp., E. coli, Proteus mirabilis, and Staphylococcus spp.

- (iii) Limitations. Use for 5 to 7 days or 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
 - (2) [Reserved]

[57 FR 37320, Aug. 18, 1992, as amended at 62 FR 13302, Mar. 20, 1997; 67 FR 67521, Nov. 6, 2002; 68 FR 54658, Sept. 18, 2003; 68 FR 55824, Sept. 29, 2003]

§ 520.88g Amoxicillin trihydrate and clavulanate potassium film-coated tablets.

- (a) Specifications. Each tablet conamoxicillin trihydrate tains clavulanate potassium, equivalent to either 50 milligrams of amoxicillin and 12.5 milligrams clavulanic acid, or 100 milligrams of amoxicillin and 25 milligrams clavulanic acid, or 200 milligrams amoxicillin and 50 milligrams clavulanic acid or 300 milligrams amoxicillin and 75 milligrams clavulanic acid.
- (b) Sponsor. See No. 000069 in $\S510.600$ (c) of this chapter.
- (c) Conditions of use—(1) Dogs—(i) Amount. 6.25 milligrams (equivalent to 5 milligrams amoxicillin and 1.25 milligrams clavulanic acid) per pound of body weight twice daily.
- (ii) Indications for use. Treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of beta-lactamase (penicillinase) Staphylococcus aureus, nonbeta-lactamase S. aureus, Staphylococcus spp., Streptococcus spp., and Escherichia coli. Treatment of periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.
- (iii) Limitations. Wounds, abscesses, cellulitis, and superficial/juvenile pyoderma: Treat for 5 to 7 days or for 48 hours after all signs have subsided. If no improvement is seen after 5 days of treatment, discontinue therapy and reevaluate diagnosis. Deep pyoderma may require treatment for 21 days; do not treat for more than 30 days. Not for